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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,787	05/23/2005	Brian F. O'Dowd	3477-110	3131
20792	7590	05/23/2006	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			ULM, JOHN D	
PO BOX 37428			ART UNIT	PAPER NUMBER
RALEIGH, NC 27627			1649	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/509,787	O'DOWD ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	John D. Uilm	1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

**Continuation of Disposition of Claims:** Claims pending in the application are 1,2,4-6,8,11,16-20,27,30,31,34,37-41,43,46-49,56,59,61,62,64-66,68,74-77,84,87,90-93,96,97,99-101,103,106,112-115 and 122.

**Continuation of Disposition of Claims:** Claims subject to restriction and/or election requirement are 1, 2, 4-6, 8, 11, 16-20, 27, 30, 31, 34, 37-41, 43, 46-49, 56, 59, 61, 62, 64-66, 68, 74-77, 84, 87, 90-93, 96, 97, 99-101, 103, 106, 112-115 and 122 .

1) Claims 1, 2, 4 to 6, 8, 11, 16 to 20, 27, 30, 31, 34, 37 to 41, 43, 46 to 49, 56, 59, 61, 62, 64 to 66, 68, 74 to 77, 84, 87, 90 to 93, 96, 97, 99 to 101, 103, 106, 112 to 115 and 122 are pending in the instant application.

2) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For example, claim 41, the text in line 8 on page 9 and the table on page 83 of the instant specification make reference to a plurality of amino acid sequences without employing the required sequence identifiers. Correction is required. See M.P.E.P. 2422.03.

3) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 4 to 6, 8, 11, 16 to 20, 27, 30, 31and 34, drawn to a receptor binding assay employing a transmembrane protein containing a nuclear translocating sequence (NLS) and a detectable moiety. It is noted that claim 4 indicates that some transmembrane proteins inherently contain NLSs. It is further noted that the employment of the combination of a transmembrane protein and a detectable moiety such as green fluorescent protein (GFP) in a receptor assay wherein a change in the distribution of the detectable moiety in response to ligand activation of the receptor was

well known in the art prior to the instant invention, as indicated by the text in lines 24 to 26 on page 3 of the instant specification.

Group II, claims 37 to 41, 43, 46 to 49, 56 and 59, drawn to a receptor binding assay employing a transmembrane protein containing a nuclear translocating sequence (NLS) in combination with a labeled ligand, wherein the transmembrane protein is not required to contain a detectable moiety.

Group III, claims 61, 62, 64 to 66, 68, 74 to 77, 84, 87, 90, drawn to a transfected cell containing a nucleotide sequence encoding a nuclear translocating sequence (NLS) and a detectable moiety. Applicant is advised the limitations of the transmembrane protein do not distinguish the claimed cell from a cell containing an exogenous nucleic acid encoding a transmembrane protein that naturally contains a NLS. The limitation "detectable moiety" encompasses any antigenic determinant that is part of the native structure of the transmembrane protein. Claim 61 encompasses a cell containing an exogenous nucleic acid encoding the angiotensin type 1 (AT<sub>1</sub>) receptor described in the third paragraph on page 8 of the instant specification.

Group IV, claim 91, drawn to a compound of unspecified constitution. This claim encompasses any compound that is a native ligand of a transmembrane protein, including dopamine, glutamate, adrenaline, serotonin, etc.

Group V, claims 92 to 96, 97, 99 to 101, 103, 106, 112 to 115 and 122, drawn to an assay that measures the interaction of a transmembrane protein containing an NLS with a second protein containing a detectable moiety. Claim 92 would encompass the method of the Barak et al. patent described on page 3 of the instant application if it is

applied to the angiotensin type 1 (AT<sub>1</sub>) receptor described in the third paragraph on page 8 of the instant specification.

The inventions listed as Groups I to V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the methods of inventions I, II and V do employ a common group of elements that distinguishes them as a group from the prior art and they have different modes of operation. These three different methods do not all require the products of inventions III and IV, which do not appear to be novel.

This application contains claims directed to more than one disclosed species of NLS as listed claim 6 and Table 1 of the instant application, in and more than one disclosed of transmembrane protein as listed, for example, in claims 19 and 20. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1649

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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